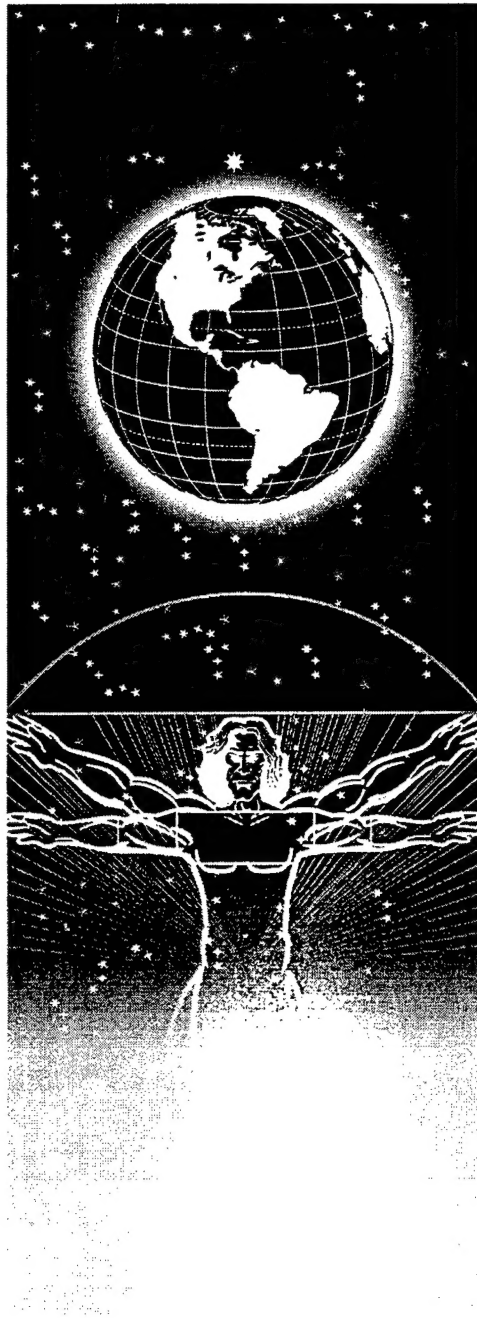


**UNITED STATES AIR FORCE
RESEARCH LABORATORY**



**TESTING AND EVALUATION OF THE
CDI™ 3M HEALTH CARE CDI™ 400
EXTRACORPOREAL BLOOD GAS
MONITORING SYSTEM**

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TESTING AND EVALUATION OF THE CDI, 3M HEALTH CARE CDI™ 400 EXTRACORPOREAL BLOOD GAS MONITORING SYSTEM

BACKGROUND

HSD/YAM requested on behalf of the of Wilford Hall Medical Center's Extracorporeal Membrane Oxygenation (ECMO) team to evaluate the CDI™ 300 Extracorporeal Blood Gas Monitoring System for use on board USAF aeromedical evacuation aircraft. The CDI™ 300 did not pass Electromagnetic compatibility testing and was replaced with a the CDI™ 400 Extracorporeal Blood Gas Monitoring System. This device is one of the components of the Neonatal/Pediatric ECMO system. Specific components of the CDI™ 400 Extracorporeal Blood Gas Monitoring System that underwent the evaluation process included the following: CDI™ Monitor, Model 400, Serial No. 5631 with Arterial and Venous Standard Reference Sensors, and CDI™ Battery Charger/AC Adapter Model 8310. Throughout this report, the term Equipment Under Test (EUT) refers to the CDI™ 400 Extracorporeal Blood Gas Monitoring System.

DESCRIPTION

The EUT provides continuous, on-line monitoring of extracorporeal pH, PCO_2 , PO_2 , temperature, calculated arterial base excess (BE) or bicarbonate (HCO_3), and venous oxygen saturation (S_vO_2). The EUT is intended for use during cardiopulmonary bypass procedures when continuous blood gas and pH monitoring is desired. The EUT utilizes a microprocessor-based monitor and optical fluorescence technology. The fiberoptic cable assemblies (one venous and one arterial) connect the monitor to a disposable sensor and flow-through cell inserted into the extracorporeal circuit. Light pulses originating from a flash lamp located in the monitor pass through optical filters so light pulses of a specific frequency are transmitted down the fiberoptic bundles to the microsensors. The microsensors are composed of fluorescent chemicals which emit light in response to the stimulating pulses. The intensity of this emitted light depends upon the concentration of oxygen, carbon dioxide, and hydrogen ions passing through the gas-and ion-permeable membrane. The light emitted by the fluorescent microsensors is returned to the monitor through receiving optical fibers in the fiberoptic bundle. A filter is used to isolate the specific frequencies of interest from the returning light spectrum for measurement by a light detector. The output signal of the detector is converted by the microprocessor to a numerical readout in millimeters of mercury (mm Hg), kilopascals (kPa), or pH units which is displayed on the face of the monitor. The EUT also displays calculated values for either the arterial base excess (mEq/L) or arterial bicarbonate concentration (mEq/L) and venous hemoglobin O_2 saturation (%). The EUT (Figure 1) operates from 115 VAC / 60 Hz power and weighs 16.3 lbs. The dimensions are 9.5 in. H. X 9.75 in. W. X 9 in. D.



Figure 1. CDI™ 400 Extracorporeal Blood Gas Monitoring System

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 5), various military standards (2-4 & 6-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check were developed specific to this EUT to verify its proper functioning under various testing conditions. Unless otherwise noted, all testing is conducted and monitored by Aeromedical Research personnel assigned to the Flight Stress Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration

3. Electromagnetic Interference (EMI)
4. Thermal/Humidity Environmental Conditions, encompassing:
 - a. Hot Operation
 - b. Cold Operation
 - c. Humidity Operation
5. Hypobaric Conditions
 - a. Cabin Pressure/Altitude
 - b. Rapid Decompression to Ambient Pressure
6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

- a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.
- b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (2); AFI 41-201, Equipment Management in Hospitals (3). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.
- c. The EUT was examined to ensure it met basic requirements for human factors design as outlined in MIL-STD 1472 (4).
- d. A test setup and performance check were developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

Place EUT on a flat surface and connect the arterial and venous standard reference sensors. Ensure the standard reference sensors (SRS) are correctly in place on the fiberoptic cable connectors and that the monitor is powered off. Turn on the monitor, a brief self-test will illuminate all indicator lights. After completion of the SRS test, the monitor will display three-digit numbers in each of the pH, PCO₂, and PO₂ display windows. After approximately 30 seconds, a message will be printed on the monitor's printer, indicating either that the SRS check was successful or that one or more of the SRS values were out of range.

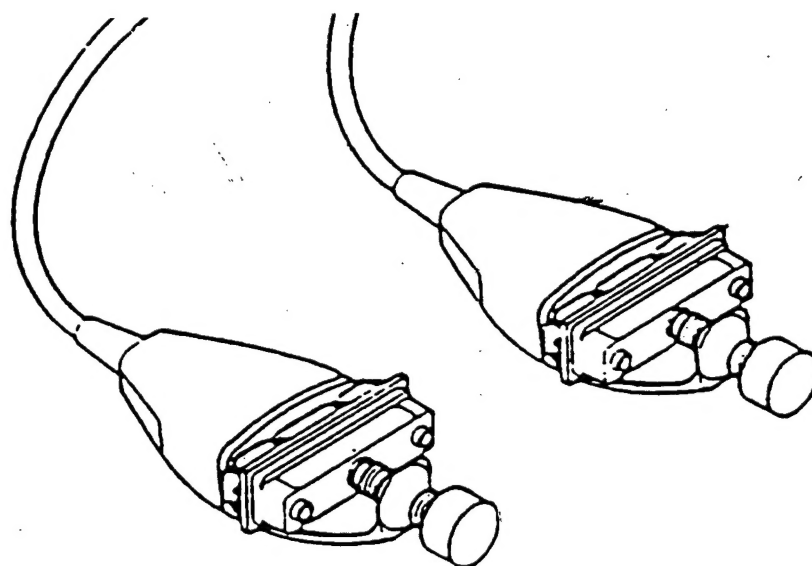


Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions. Verify that the SRS self check has been successfully completed by observing the printed "All SRS Values In Range" message. If the SRS check is not completed, there is no way to verify whether or not there has been electronic or optical drift in the monitor that could result in calibration failure or reduced blood gas measurement accuracy. Document values and ensure that they are within 10 % of baseline values.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted using a calibrated Unholtz-Dickie Vibration System, controller model UD-VWIN and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT was secured directly to the vibration system adapter/mounting plate. It was subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

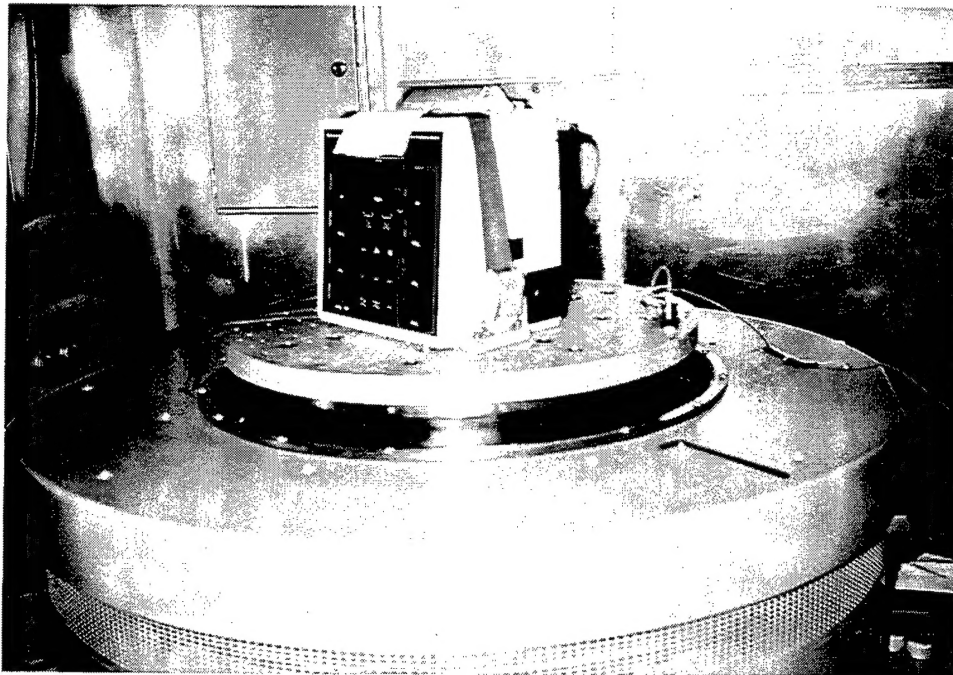


Figure 3. Vibration Table Mounting

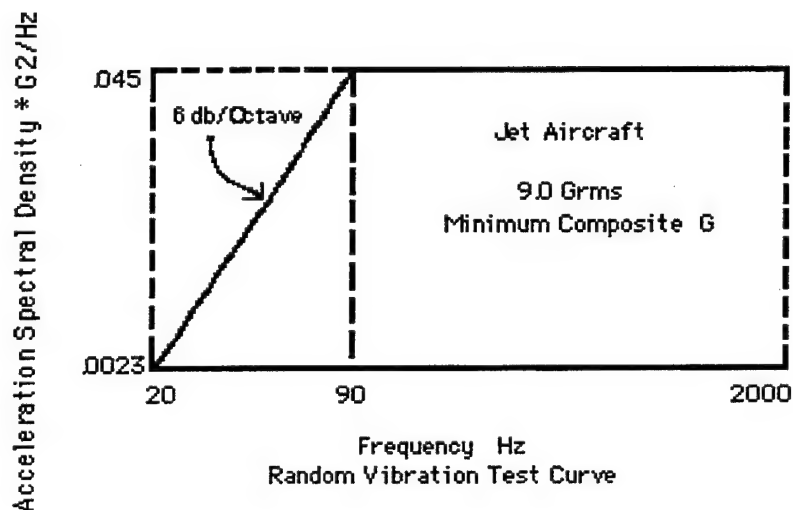
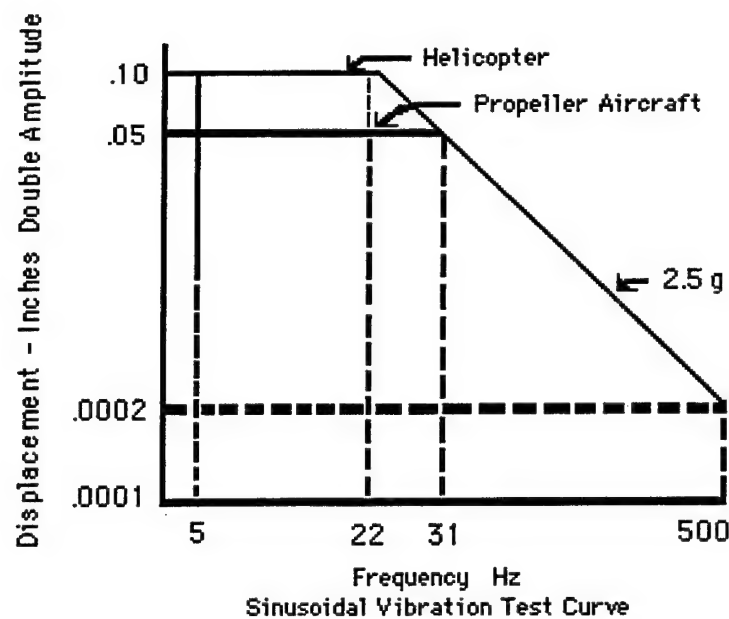


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor to assessing the effects of excessive electromagnetic emissions, a source of potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the equipment during operation. It verifies the device's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the medical device along its power supply lines. It was performed to assess the device's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the device's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Air Force Research Laboratory's A-7 Environmental Chamber. The EUT was placed in the center of the calibrated environmental chamber. During environmental testing the EUT was monitored continuously, and a performance check was conducted every 15 minutes. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hours
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hours
- c. Modified Hot Temp Operation: $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hours
- d. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hours

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground, at rates of 5,000 ft/min. Descent is stopped at 2,000 ft for performance checks.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not endanger a patient, personnel, or the aircraft itself. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 40,000 ft over a period of 60 seconds, held at 40,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice more; once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions; performance checks were assessed each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research verifies demonstration of all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members from Aeromedical Research on C-9 and C-141 aeromedical evacuation missions. The EUT was positioned and secured to the neonatal/pediatric ECMO transport cart and evaluated. Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from ECMO team members, and other aeromedical evacuation crew members participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits.

VIBRATION

The EUT operated satisfactorily during vibration testing.

ELECTROMAGNETIC COMPATIBILITY

The CDI™ 400 had excessive radiated emissions in the HF, VHF FM/AM, Localizer, and Marker Beacon bands. WL/AASW modified the EUT by improving to the EUT's container shielding. The shield was improved by eliminating gaps in the shield and by reducing the gap between the front and the back container assemblies. This resulted in a 20dB reduction in radiated emissions. The shielding consisted of using Scotch™3M Type 1245 copper tape, nomenclature: embossed, copper foil, with acrylic pressure sensitive adhesive, flame retardant. Once the container was disassembled, the tape was secured to each half of the container.

ASC/ENAI, Wright-Patterson AFB certified the EUT per AFI 11-206 for operation during all phases of flight on all Air Force aircraft while operating from 115 VAC / 60 Hz & battery power. All other CDI™ 400 Monitors are not certified for use below 10,000 feet above ground level (AGL), as their emissions exceed the limits of MIL-STD-461D.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT operated satisfactorily during hot, cold, and humidity operation testing.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT operated satisfactorily during hypobaric testing.
2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on C-9 and C-141 aeromedical evacuation missions. The EUT was secured to the Neonatal/Pediatric ECMO Patient Transport Cart as one of the components of the Neonatal/Pediatric ECMO system. Evaluation confirmed that the unit would operate successfully during all phases of flight.

SUMMARY

Aeromedical Research found the modified CDI™ 400 Extracorporeal Blood Gas Monitoring System, Serial No. 5631 to be acceptable for all phases of flight on all Air Force aircraft while operating from 115 VAC / 60 Hz and battery power.

All unmodified CDI™ 400 Extracorporeal Blood Gas Monitoring Systems are conditionally acceptable for use. Unmodified CDI™ 400 Monitors are not certified for use below 10,000 feet, as their emissions exceed the limits of MIL-STD-461D. This means that an unmodified CDI™ 400 must be turned off during takeoff and landing. The CDI™ 400 Monitor may be shut off without loss of the most recent calibration data (9). It may only be used inflight on all Air Force aircraft while operating from 115 VAC / 60 Hz and battery power.

The CDI™ 400 operation was within expected parameters when subjected to vibration, electromagnetic Interference (EMI), environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The following requirements apply:

- a. Set up and operated by ECMO team members
- b. Positioned and secured to the neonatal/pediatric ECMO transport cart

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. AFI 41-203, Electrical Shock Hazards
3. AFI 41-201, Equipment Management in Hospitals
4. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. Emergency Care Research Institute (ECRI)
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. CDI, 3M Health Care, CDI™ 400 Extracorporeal Blood Gas Monitoring System, Operators Manual.
10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX
CDI, 3M HEALTH CARE
CDI™ 400 EXTRACORPOREAL
BLOOD GAS MONITORING SYSTEM
SPECIFICATIONS

Physical

Size	9.5 in. H. X 9.75 in. W. X 9 in. D.
Weight	16.3 lbs

System Operating Ranges

pH:	6.8 to 7.8 pH units
PCO ₂	10 to 80 mm Hg (1 to 11 kPa)
Arterial PO ₂	60 to 500 mm Hg (8 to 69 kPa)
Arterial PO ₂	20 to 100 mm Hg (2 to 14 kPa)
BE	-25 to 25 mEq/liter
HCO ₃	0 to 50 mEq/liter
S _v O ₂	0 to 100%
Temperature	15° to 45° C

Electrical

Monitor Power	12 volt, 6 amp-hour rechargeable battery or via line power using battery charger/AC adapter
Leakage Current	10 microamp maximum

Environment

Temperature	15° to 35° C (59° to 95° F)
Humidity	10 to 80%